



AMENDMENTS TO THE CLAIMS

Please amend the claims so that they read as follows:

Claims 1-10 (Canceled)

Claim 11 (Original): Sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]-butanoate pentahydrate.

Claim 12 (Original): A crystalline polymorph of a pentahydrate of sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate exhibiting an X-ray powder diffraction pattern substantially as shown in Figure 4.

Claim 13 (Original): A crystalline polymorph of a pentahydrate of sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate exhibiting an X-ray powder diffraction pattern having peaks in degrees $2\Theta \pm 0.2^\circ$ 2Θ at 5.47, 10.2, 16.3, 19.8, 21.7, 23.5, 27.3, 28.9, 30.6, and 33.3.

Claim 14 (Original): The crystalline polymorph of claim 13, wherein the crystalline polymorph has a melting point onset as determined by differential scanning calorimetry at about 213.05°C.

Claim 15 (Original): A crystalline polymorph of anhydrous sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate exhibiting an x-ray powder diffraction pattern substantially as shown in Figure 5.

Claim 16 (Original): A crystalline polymorph of anhydrous sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate exhibiting an x-ray powder diffraction pattern having peaks in degrees $2\Theta \pm 0.2^\circ$ 2Θ at 9.1, 12.3, 17.9, 19.8, 23.0, 24.1, 24.4, 26.1, 28.2, and 28.5.

Claim 17 (Original): The crystalline polymorph of claim 16, wherein the crystalline polymorph has a melting point onset as determined by differential scanning calorimetry at about 222.02°C.

Claim 18 (Original): Amorphous sodium 4-CNAB.

Claim 19 (Previously Presented) A composition comprising:

- (a) a crystalline polymorph of any one of claims 11, 15, and 18; and
- (b) a biologically active agent.

Claim 20 (Original): The composition of claim 19, wherein the biologically active agent comprises at least one protein, polypeptide, peptide, hormone, polysaccharide, mucopolysaccharide, small polar organic molecules, carbohydrate, or lipid.

Claim 21 (Original): The composition of claim 19, wherein the biologically active agent is selected from the group consisting of growth hormones, human growth hormones (hGH), recombinant human growth hormones (rhGH), bovine growth hormones, porcine growth hormones, growth hormone-releasing hormones, interferons, α -interferon, β -interferon, γ -interferon, interleukin-1, interleukin-2, insulin, porcine insulin, bovine insulin, human insulin, human recombinant insulin, insulin-like growth factor(IGF), IGF-1, heparin, unfractionated heparin, heparinoids, dermatans, chondroitins, low molecular weight heparin, very low molecular weight heparin, ultra low molecular weight heparin, calcitonin, salmon calcitonin, eel calcitonin, human calcitonin, erythropoietin (EPO), atrial naturetic factor, antigens, monoclonal antibodies, somatostatin, protease inhibitors, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, leutinizing-hormone-releasing-hormone, follicle stimulating hormone, glucocerebrosidase, thrombopoietin, filgrastim, prostaglandins, cyclosporin, vasopressin, cromolyn sodium, sodium chromoglycate, disodium chromoglycate, vancomycin, desferrioxamine, bisphosphonates, alendronate, tiludronate, etidronate, clodronate, pamidronate, olpadronate, incadronate, BIBN-4096BS, parathyroid hormone, fragments of parathyroid hormone, antimicrobials, daptomycin, anti-fungal agents, vitamins, analogs, fragments, mimetics and polyethylene glycol-modified derivatives of these compounds, and any combination thereof.

Claim 22 (Previously Presented): A composition comprising

- (a) a crystalline polymorph of any one of claims 11, 15, and 18; and
- (b) insulin.

Claim 23 (Original): A dosage unit form comprising:

- (A) the composition of claim 19; and
- (B)
 - (a) an excipient
 - (b) a diluent,
 - (c) a disintegrant,
 - (d) a lubricant,
 - (e) a plasticizer,
 - (f) a colorant,
 - (g) a dosing vehicle, or
 - (h) any combination thereof.

Claim 24 (Original): A dosage unit form comprising:

- (A) the composition of claim 22; and
- (B)
 - (a) an excipient
 - (b) a diluent,
 - (c) a disintegrant,
 - (d) a lubricant,
 - (e) a plasticizer,
 - (f) a colorant,
 - (g) a dosing vehicle, or
 - (h) any combination thereof.

Claim 25 (Original): A method of administering an active agent to an animal in need thereof, the method comprising the step of administering the composition of claim 19 to the animal.

Claim 26 (Original): A method of treating diabetes in an animal in need thereof, comprising the step of administering a composition of claim 22 to the animal.

Claim 27 (Original): A method of treating diabetes in a human in need thereof, comprising the step of administering a composition of claim 22 to the human.

Claims 28-33 (Canceled)

Claim 34 (Original): A method of preparing Form IV of sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate comprising the step of exposing Form I, II, III or V of sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate or a mixture thereof to a relative humidity of at least about 75% for a time sufficient to yield Form IV of sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate.

Claim 35 (Original): A method of preparing Form IV of sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate comprising the step of heating Form III of sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate to a temperature between about 160° C and the melting point of anhydrous sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate in an environment free of air and water.

Claim 36 (Original): A method of preparing amorphous sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate comprising the step of solidifying a melt of sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate.

Claim 37 (Original): A method of preparing amorphous sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate comprising the step of lyophilizing sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate.

Claim 38 (Original): A method of preparing amorphous sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate comprising the step of recrystallizing sodium 4-[(4-chloro-2-hydroxybenzoyl)amino]butanoate in an aqueous alcohol solution, where the molar ratio of alcohol to water is greater than 1.

Claim 39 (Original): The method of claim 38, wherein the molar ratio is greater than 10.

Claim 40 (New): A composition comprising:

- (a) a crystalline polymorph of claim 15; and
- (b) a biologically active agent.

Claim 41 (New): A composition comprising

- (a) a crystalline polymorph of claim 15; and
- (b) insulin.